

ADSOL RED CELL PRESERVATION SOLUTION SYSTEM IN PLASTIC CONTAINER (PL 146 PLASTIC)- anticoagulant citrate phosphate dextrose (cpd) solution and adsol preservation solution
Fenwal, Inc.

BLOOD-PACK™ Unit with an Integral SEPACELL™ FLEX-EXCEL™ Leukocyte Reduction Filter Using CPD/ADSOL™ Red Cell Preservation Solution for Whole Blood Collection and Filtration of Red Blood Cells

Rx only

Contains Y-Sampling Site for the collection of unanticoagulated whole blood samples for laboratory testing and the DONORCARE™ Needle Guard.

Integral filter unit intended for leukocyte reduction of AS-1 red blood cells:

- At ambient temperature up to 8 hours after blood collection.
- At refrigerated temperature up to 3 days after blood collection if AS-1 red blood cells are prepared within 3 days after whole blood collection.

The leukocyte reduced red blood cells may then be stored for the maximum allowable dating period.

Instructions for Use

Collection Procedure:

Use aseptic technique.

Note: Nominal tubing dimensions of product are 0.118" inner diameter x 0.025" wall thickness.

Note: If the Y-Sampling Site is not used, donor samples may be collected using an alternate method following standard procedures.

Precautions:

- **Do not use unless the solutions are clear.**
 - **Before beginning procedure, obtain one access device for each BLOOD-PACK™ unit with Y-Sampling Site to be processed.**
1. Identify BLOOD-PACK unit using appropriate donor identification system.
 2. Adjust donor scale to desired collection weight and position primary container on the donor scale as far as possible below donor arm.
 3. Clamp donor tubing between needle and primary container. This step may be performed prior to step 1 or 2.
 4. Apply pressure to donor's arm and disinfect site of venipuncture.
 5. If blood pressure cuff is used, inflate to approximately 60 mmHg.
 6. Remove needle cover per instructions below:
 - a) Holding the hub and cover near the tamper-evident seal, twist cover 1/4 turn to break seal.
 - b) Remove needle cover, being careful not to drag the cover across the needle point.
 7. Perform venipuncture, appropriately secure donor needle and/or tubing and release clamp on donor tubing.
 8. When good blood flow is established, slide the DONORCARE™ needle guard over the needle

hub into the engaged position. Leave the front third of the needle hub exposed for access. Stabilize the front of the needle guard to arm with tape (see Figure 1).

Note: In difficult collection conditions (e.g., slow blood flow), leave the needle guard disengaged behind the hub during collection. **Engage the needle guard at the end of blood collection.**

9. **Mix blood and anticoagulant in primary container at several intervals during collection and immediately after collection.**
10. Collect the appropriate volume based on BLOOD-PACK unit used.
Note: The volume of anticoagulant is sufficient for the blood collection indicated on BLOOD-PACK unit \pm 10%.
11. Release the pressure on the donor's arm as appropriate.

Precaution: Do not proceed with the remaining steps until the entire whole blood unit is collected.

12. To avoid possible contamination of the whole blood unit, before filling whole blood sample tubes, hermetically seal the donor tubing near the Y-Sampling Site on the side leading to the primary container using a metal clip or appropriate alternate method.

Precaution: Complete steps 13 - 22 within approximately 4 minutes after sealing the donor tubing to avoid possible clot formation in the tubing.

13. To collect samples, insert the access device by pushing firmly into the Y-Sampling Site until the membrane seal is penetrated (see Figure 2).

Note: If the access device is assembled such that the outer barrel is screwed onto the Luer, make sure to rotate clockwise upon insertion to avoid barrel detaching from Luer.

14. Open the cap on the access device (if applicable).
15. Directly align the vacuum sample tube with the internal needle in the access device. Insert vacuum sample tube into device until the stopper is punctured.
16. Allow vacuum sample tube to fill with blood then remove from the access device.
17. Repeat steps 15 and 16 until the desired number of vacuum sample tubes have been filled.

Notes:

- **If the access device needs to be replaced, use a hemostat to clamp the tubing between the needle and the Y-Sampling Site. Then, grasp base of Sampling Site with one hand and pull the access device out with the other hand. Firmly insert the new access device. Remove hemostat and continue sampling.**
- **If the access device is assembled such that the outer barrel is screwed onto the Luer, make sure to rotate clockwise upon removal to avoid barrel detaching from Luer.**
- **The access device can only be replaced one time.**

Precaution: When replacing the access device, be careful to avoid contact with any blood droplets on the Luer or Sampling Site. Discard used access device appropriately.

18. Release remaining pressure on donor's arm.
19. If desired, apply hemostat to donor tubing between needle and Y-Sampling Site.
20. **Withdrawal of Needle** (see Figure 3)

Precaution: The needle guard must be held stationary while the needle is withdrawn into it.

- a) Place folded sterile gauze over puncture site and hold in place with finger tip without exerting pressure.
- b) Hold sides of needle guard near the front, between the index finger and thumb. Pull the tubing smoothly until the needle is locked into the needle guard.
- c) Confirm the needle lock by:
 - Listen for the 2nd “click” as the needle is drawn into the needle guard.
 - Ensure the tubing cannot be pulled through the needle guard.

21. Remove and discard the Y-Sampling Site and needle guard into an appropriate biohazardous waste container following established procedures. If donor tubing is also to be discarded, hermetically seal donor tubing directly above the primary container and remove.

Note: Step 22 may be performed prior to step 21 if desired.

22. If the donor tubing is not hermetically sealed directly above the primary container, then strip the blood from the remaining donor tubing into the primary container. Mix and allow tubing to refill; repeat once.

Component Preparation:

Notes:

- If a platelet concentrate is to be prepared, it should be separated within 8 hours after blood collection.
- Fresh frozen plasma should be separated from the red blood cells and placed in the freezer at -18°C or colder within 8 hours after blood collection.
- ADSOL™ red cell preservation solution should be added to the red blood cells immediately after the removal of plasma. Preparation of AS-1 red blood cells may vary depending on processing option selected:
 - a) Within 8 hours of blood collection if whole blood is held at ambient temperature.
 - b) Within 3 days of blood collection if whole blood is refrigerated.

23. At the appropriate time, prepare the BLOOD-PACK unit with Integral Filter for centrifugation.

Note: Steps 24 through 30 provide one method for centrifuge cup loading.

24. Thoroughly mix the primary container end over end.
25. Place the filter unit on a work surface, and arrange the containers with the bottoms of the containers (hanger edge) closer to the front of the work surface and the tops of the containers (tab edge) farther away.
26. Place empty satellite container(s) and the ADSOL red cell preservation solution container on top of each other, and keep post filtration red cell storage container separate. Align the breakaway cannula and the check valve near the top of the post filtration red cell container. Fold the container port over both the check valve and cannula to secure.

Note: Do not place filter, breakaway cannula or check valve on lower half of the container. Check valve must be placed in a horizontal position (Figure 4a). Avoid the clear (red tip) side from pointing downward (Figure 4b).
27. Place filter on top of folded container, which encloses breakaway cannula and check valve. Gather all the tubing and place it on top of filter. Fold over the ports of the ADSOL red cell preservation solution container and empty satellite container(s), then place on top of the gathered tubing.

28. Place the entire set of gathered bags, tubing and filter on top of whole blood container with the base label of the post filtration red cell storage container facing out.
Note: Steps 26-28 may be performed in the reverse order. The specific stacking order and methodology may also vary depending on the workstation setup and centrifuge equipment used.
29. Holding the bundle of containers by the sides of the stack, squeeze the bundle firmly and slide it into the centrifuge cup.
Note: Ensure that the filter, breakaway cannula and check valve do not move to the lower portion of the centrifuge cup when loading. Failure to properly orient these components during centrifugation can result in damage.
Note: The tabs of the containers may be tucked inward to avoid the unit from interfering with free movement of the cup.
30. Verify that the top edge of the filter is level with, or below, the top of the centrifuge cup. Any excess tubing should be pushed down into the centrifuge cup.
31. Perform centrifugation according to center procedures.
32. Following centrifugation, remove containers from the centrifuge cup taking care not to disturb the red blood cell / plasma interface.
33. Place primary container in a plasma extractor and apply pressure. Open the cannula on the top of the primary container to transfer plasma into the empty TRANSFER-PACK™ container.
34. When the desired amount of plasma has been removed, clamp the tubing between the plasma container and the Y-connector closest to the plasma container and release pressure on the primary container.
35. Suspend the ADSOL red cell preservation solution container, open the cannula on the ADSOL solution container and drain the contents into the primary container of the CPD red blood cells. Clamp the ADSOL red cell preservation solution tubing.
36. Hermetically seal and separate the tubing between the Y-connectors or above the plasma TRANSFER-PACK™ container. Be careful to avoid fluid splatter.
37. Mix the ADSOL red cell preservation solution and red cells thoroughly.
Note: If the ADSOL red cell preservation solution is not added to the red cells, ensure appropriate labeling of the red cell container. The pre-filter container does not include tubing with segment numbers. A CPD red cell without ADSOL red cell preservation solution may be stored between 1 and 6°C up to 21 days after collection. The attached SEPACELL™ FLEX-EXCEL™ filter should not be used to leukoreduce a CPD red cell without ADSOL red cell preservation solution.

Filtration Procedure:

Precaution: Red blood cell products collected from certain donors may have extended filtration times and the potential for ineffective filtration and leukoreduction.

38. **Mix unfiltered AS-1 red blood cells thoroughly.** Invert the unfiltered AS-1 red blood cells and hang the filter set such that the filter remains vertical. To achieve maximum flow rate, allow the set to hang to full length.
Note: The storage container must remain below the level of the filter during filtration.
39. Inspect all tubing to ensure it hangs freely without kinks. If desired, a temporary clamp may be placed on the vent line, but must be removed prior to expelling air through the vent line.
40. Break the in-line cannula above the filter to start filtration.
Note: Manual or mechanical pressure should not be used to increase the flow rate through the filter.
Note: Tubing below the filter should not be stripped at any time during the filtration process.
Note: If filtration of red cells is initiated at ambient temperature, the filtration process can be completed at either ambient or refrigerated temperature prior to storing the red cells between 1

and 6°C. However, for optimal filtration time, it is recommended to complete the filtration at ambient temperature.

41. As the filtered red cell storage container is filling, or when flow stops, clamp or pinch the tubing below the filter to occlude flow.

Note: While the check valve is designed to prevent blood flow from entering the vent line below the valve, blood may flow down and fill the valve.

42. Squeeze the filtered red cell storage container to expel air from the filtered red cell container through the vent line. Continue squeezing the filtered red cell container until the vent line segments and check valve are filled with blood as desired.

43. Remove the clamp or release the tubing below the filter to resume red cell flow through the filter. If desired, the temporary clamp may be replaced on the vent line immediately after removing the clamp below the filter. When filtration is complete, air can be observed in the inlet side of the filter.

Note: While the check valve is designed to prevent blood flow from entering the vent line below the valve, it is normal for air to pass through the valve and enter the vent line tubing. To avoid air from entering the vent line below the valve, the vent line may be clamped during this step, or blood may be expressed beyond the check valve during the air expel operation.

44. Hermetically seal and detach the tubing below the filter. Also, hermetically seal and detach the vent line between the one way valve and the top donor segment number.
45. Make segments from the vent line tubing and leave segments attached to the filtered red cell storage container. (QC samples may be prepared by thoroughly mixing the filtered red cells and stripping this tubing prior to sealing the segments.)
46. Store the AS-1 red blood cells, leukocytes reduced between 1 and 6°C.
47. Infuse the red cells within 42 days of collection.

Warning: Failure to achieve closed system processing conditions negates the extended storage claim and the red blood cell product must be transfused within 24 hours.

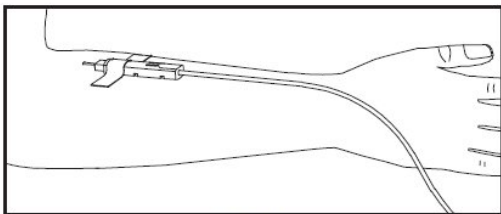


Figure 1

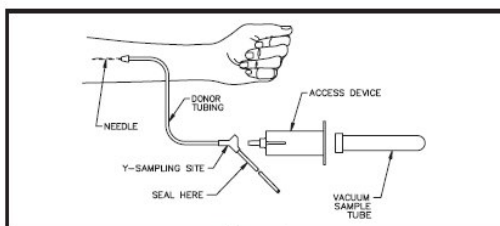


Figure 2

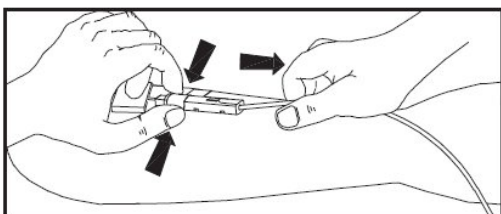
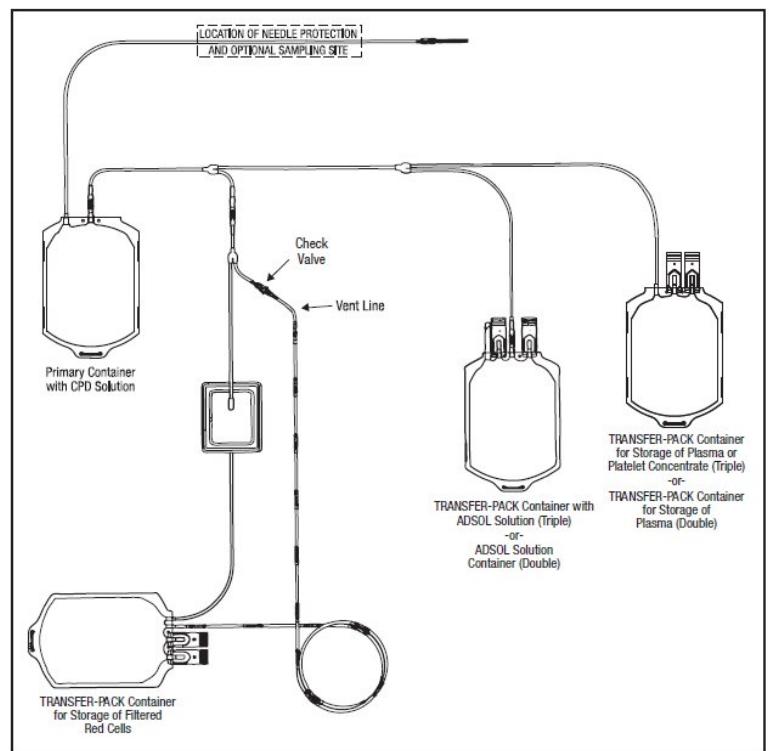


Figure 3



Representative Product Drawing

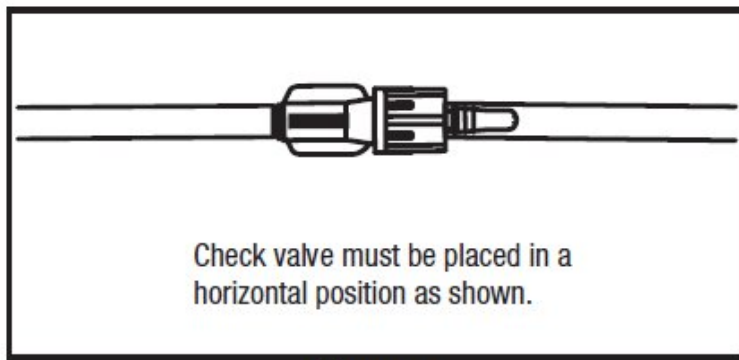


Figure 4a

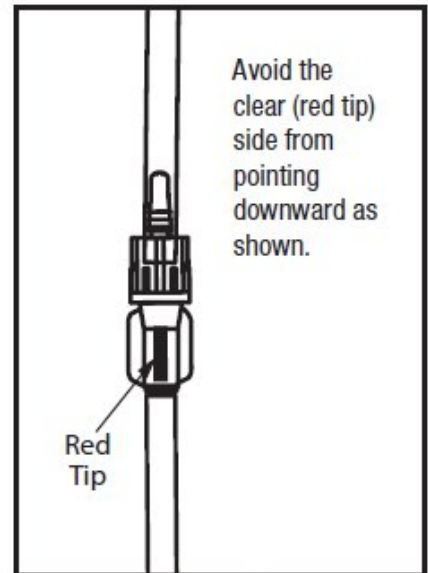


Figure 4b

Store at Controlled Room Temperature.
 USP Definition of “Controlled Room Temperature”
 United States Pharmacopeia, General Notices.
 United States Pharmacopeial Convention, Inc.
 12601 Twinbrook Parkway, Rockville, MD



Fenwal, Inc.

Lake Zurich, IL 60047 USA

Made in USA

1-800-933-6925

07-19-07-272 REV: A

11/2012



Manufacturer

FENWAL, BLOOD-PACK, TRANSFER-PACK, ADSOL, and FLEX-EXCEL are trademarks of Fenwal, Inc.

SEPACELL is a trademark of Asahi Kasei Medical Co., Ltd.

DONORCARE is a trademark of ITL Corporation.

© 2012 Fenwal, Inc. All rights reserved.

PACKAGE/LABEL DISPLAY PANEL

Code 4R1584

10 Units

Fenwal™

**Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK™ Unit;
 TRANSFER-PACK™ Container with ADSOL™ Red Cell Preservation Solution; Integral
 SEPACELL™ FLEX-EXCEL™ Red Cell Leukocyte Reduction Filter**

Triple For the Collection and Processing of 500 mL Blood
Y-Sampling Site, DONORCARE™ Needle Guard, 16 ga. Ultra Thin Wall Needle

Rx only

Each unit consists of a PL 146 Plastic primary container with 70 mL of CPD solution containing 1.84 g Sodium Citrate (dihydrate) USP, 1.78 g Dextrose (monohydrate) USP, 209 mg Citric Acid (anhydrous) USP, 155 mg Monobasic Sodium Phosphate (monohydrate) USP, pH may have been adjusted with sodium hydroxide; one 400 mL PL 146 Plastic TRANSFER-PACK container with 110 mL of ADSOL Red Cell Preservation Solution containing 2.42 g Dextrose (monohydrate) USP, 990 mg Sodium Chloride USP, 825 mg Mannitol USP, 30 mg Adenine USP; one empty 400 mL PL 1240 Plastic TRANSFER-PACK container; one integral SEPACELL FLEX-EXCEL Red Cell Leukocyte Reduction Filter and one empty 450 mL PL 146 Plastic TRANSFER-PACK container for the storage of AS-1 red blood cells, leukocytes reduced.

Sterile, non-pyrogenic fluid path
See instructions for use.

Store at Controlled Room Temperature (refer to direction insert).

- Open pouch by tearing across at notch.
- Direct handling of product surfaces prior to extended storage in the **foil** pouch, may result in mold growth.
- Unused units in open **foil** pouch may be kept up to 60 days by folding and **securing** open end of **foil** pouch to prevent possible loss of moisture, provided:
 - I) Units are not removed from **foil** pouch, or
 - II) Unused units removed from **foil** pouch are returned to the **foil** pouch within 12 hours. Units may be removed from the pouch and returned only once.
- Units removed from the **foil** pouch (that are not returned to the pouch within 12 hours) must be used within 4 days (96 hours). Units out of the **foil** pouch for longer than 96 hours must be discarded.

FENWAL, BLOOD-PACK, ADSOL, TRANSFER-PACK and FLEX-EXCEL are trademarks of Fenwal, Inc.

SEPACELL is a trademark of Asahi Kasei Medical Co., Ltd.

DONORCARE is a trademark of ITL Corporation.



Fenwal, Inc.

Lake Zurich, IL 60047 USA

Made in USA

07-28-05-513 REV: A



Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) BLOOD-PACK™ Unit; TRANSFER-PACK™ Container with ADSOL™ Red Cell Preservation Solution; Integral SEPACELL™ FLEX-EXCEL™ Red Cell Leukocyte Reduction Filter

Triple For the Collection and Processing of 500 mL Blood
Y-Sampling Site, DONORCARE™ Needle Guard, 16 ga. Ultra Thin Wall Needle

Rx only

Each unit consists of a PL 146 Plastic primary container with 70 mL of CPD solution containing 1.84 g Sodium Citrate (dihydrate) USP, 1.78 g Dextrose (monohydrate) USP, 209 mg Citric Acid (anhydrous) USP, 155 mg Monobasic Sodium Phosphate (monohydrate) USP, pH may have been adjusted with sodium hydroxide; one 400 mL PL 146 Plastic TRANSFER-PACK container with 110 mL of ADSOL Red Cell Preservation Solution containing 2.42 g Dextrose (monohydrate) USP, 990 mg Sodium Chloride USP, 825 mg Mannitol USP, 30 mg Adenine USP; one empty 400 mL PL 1240 Plastic TRANSFER-PACK container; one integral SEPACELL FLEX-EXCEL Red Cell Leukocyte Reduction Filter and one empty 450 mL PL 146 Plastic TRANSFER-PACK container for the storage of AS-1 red blood cells, leukocytes reduced.

Sterile, non-pyrogenic fluid path
See instructions for use.

Store at Controlled Room Temperature (refer to direction insert).

- Open pouch by tearing across at notch.
- Direct handling of product surfaces prior to extended storage in the **foil** pouch, may result in mold growth.
- Unused units in open **foil** pouch may be kept up to 60 days by folding and **securing** open end of **foil** pouch to prevent possible loss of moisture, provided:
 - I) Units are not removed from **foil** pouch, or
 - II) Unused units removed from **foil** pouch are returned to the **foil** pouch within 12 hours. Units may be removed from the pouch and returned only once.
- Units removed from the **foil** pouch (that are not returned to the pouch within 12 hours) must be used within 4 days (96 hours). Units out of the **foil** pouch for longer than 96 hours must be discarded.



+M5264R15842+

FENWAL, BLOOD-PACK, ADSOL, TRANSFER-PACK and FLEX-EXCEL are trademarks of Fenwal, Inc. SEPACELL is a trademark of Asahi Kasei Medical Co., Ltd. DONORCARE is a trademark of ITL Corporation.



Fenwal, Inc.
Lake Zurich, IL 60047 USA
Made in USA
07-28-05-513 REV: A

ADSOL RED CELL PRESERVATION SOLUTION SYSTEM IN PLASTIC CONTAINER (PL 146 PLASTIC)

anticoagulant citrate phosphate dextrose (cpd) solution and adsol preservation solution kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0942-6470
---------------------	-------------------------	---------------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0942-6470-03	1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BAG	70 mL
Part 2	1 BAG	110 mL

Part 1 of 2

CPD

citrate phosphate dextrose solution

Product Information

Route of Administration	INTRAVENOUS	DEA Schedule	
-------------------------	-------------	--------------	--

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Trisodium Citrate Dihydrate (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	1.84 g in 70 mL
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	1.78 g in 70 mL
Anhydrous Citric Acid (UNII: XF417D3PSL) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	209 mg in 70 mL
Sodium Phosphate, Monobasic, Monohydrate (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	Sodium Phosphate, Monobasic, Monohydrate	155 mg in 70 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		70 mL in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN8 11104	03/01/2007	

Part 2 of 2

ADSOL RED CELL PRESERVATION SOLUTION SYSTEM

adsol red cell preservation solution solution

Product Information

Route of Administration	INTRAVENOUS	DEA Schedule	
-------------------------	-------------	--------------	--

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)			Dextrose Monohydrate	2.42 g in 110 mL
Sodium Chloride (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37)			Sodium Chloride	990 mg in 110 mL
Mannitol (UNII: 3OWL53L36A) (Mannitol - UNII:3OWL53L36A)			Mannitol	825 mg in 110 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)			Adenine	30 mg in 110 mL
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		110 mL in 1 BAG		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NDA	BN8 1110 4		03/01/2007	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
NDA	BN8 1110 4		03/01/2007	

Labeler - Fenwal, Inc. (794519020)

Establishment			
Name	Address	ID/FEI	Business Operations
Fenwal International		091164590	MANUFACTURE(0942-6470)